



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/541,191	10/11/95	KAYYEM J	A-62629/RFT

HM42/0911
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EXAMINER
JONES, D

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/11/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

541191

Applicant(s)

Examiner

D. Jones

Group Art Unit

1616

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/14/98
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-22 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

3. **Statutory Double Patenting**

The statutory type (35 USC 101) double patenting rejection of claims 1-4, 6-10, 12-13, 16 and 22 over claims 1-8, 12 and 21-23 of copending Serial No. 08/321, 552 is **MAINTAINED** for the reasons set forth in the Office Action mailed 7/7/97, Paper No. 9.

4. **Obviousness-type Double Patenting**

The obviousness-type double patenting rejection of claims 5, 11, 14-15 and 17-21 over claims 9-11, 24-27 and 35-38 of copending Serial No. 08/321,552 is **MAINTAINED** for the reasons set forth in the Office Action mailed 7/7/97, Paper No. 9.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al., 1991 in view of Kornguth et al. 1993.

The concept of the claimed invention is that reagents that are useful as contrast agents may be delivered to a cell of interest by linking them to cell binding reagents through multiple polymers that interact by ionic means. This concept of targeting an agent of interest to a cell is exactly what is disclosed by Wu et al. It is granted that Wu et al. do not disclose ^{the} ~~an~~ inclusion of an MRI contrast agent. However, Wu et al. is not relied upon for such a teaching. Rather, Wu et al. is relied upon to indicate that the artisan used multiple polymers of DNA and polylysine linked to a cell specific binding agent to deliver said DNA to a particular target cell that harbored a receptor for said agent. Thus, Wu et al. sets a precedent for the use of polylysine (a positively charged) agent coupled to a cell specific binding agent. Kornguth et al. Also used polylysine to delivery agents to cells to interest by binding the agent (including a contrast agent) to said polylysine.

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The instant grounds of rejection and the conclusion of obviousness is based upon the teachings of the prior art as a whole. In this case, the critical teachings is then placed in the context of Wu et al. who disclose every element of what is claimed with the exception of the inclusion of MRI contrast agent. However, since polylysine was known to have been useful as a carrier molecule of components of interest including cell targeting molecules and contrast agents and give that one would have used polylysine conjugates to deliver nucleic acids (as claimed in, e.g. claim 12) and for delivery of imaging agents, one would have arrived at the claimed invention by using polylysine functionalities for their known and expected properties. Note that Kornguth et al. specifically indicate the coupling of therapeutic agents (the DNA of Wu et al) and imaging agent (such a DTPA conjugated Gd; see e.g. col. 2, lines 57-63, and col.3, lines 31-34, and 56-60) to polylysine. Thus, it is maintained that the artisan would have arrived at the claimed invention because one would have expected that polylysine would have been useful for both purposes as suggested by the combination of art recognized functionalities.

No claim are allowable

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jones whose telephone number is (703) 308-4640.

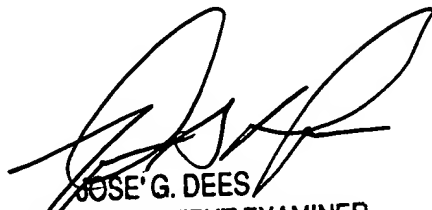
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-1235 . The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
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